Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Title	Evaluating non-surgical management of acute anterior cruciate ligament rupture with a novel brace protocol versus early surgical reconstruction – a comparative effectiveness randomised controlled trial
Short Title	The EMBRACE study
Project Number	2024.149
Project Sponsor	The University of Melbourne
Coordinating Principal Investigator / Principal Investigator	A/Prof Stephanie Filbay
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Location	The University of Melbourne

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Part 1 What does my participation involve?

1. Introduction

You are invited to take part in this research project. This is because you have torn the anterior cruciate ligament (ACL) in your knee. The research project is testing a new treatment for ACL tears called the Cross Bracing Protocol. The Cross Bracing Protocol is being compared to ACL reconstruction surgery.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research. Please read this information carefully. You are welcome to ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to have the tests and treatments that are described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2. What is the purpose of this research?

The purpose of this study is to compare two different types of treatment for recent ACL rupture.

What is an ACL injury and what are the treatment options?

The knee has a ligament called the anterior cruciate ligament (ACL), which connects the thigh bone (femur) to the shin bone (tibia). This ligament helps to stabilise the knee and stops the knee joint surfaces from sliding and twisting too far. If you tear your ACL, your knee may feel unstable, painful and swollen. The goals of treatment for an ACL tear are to make the knee stable again, improve muscle strength and function, and help people safely return to sports and other activities.

There are currently two main treatment options available in Australia – rehabilitation (rehab) without surgery and ACL reconstruction surgery. Both treatment options lead to similar levels of knee function (like using stairs and running), knee strength, activity levels, return to sport, quality of life, and knee symptoms (like pain, stiffness, swelling) at 2 and 5 years after injury. When people try rehab before considering surgery, around half of them decide to have surgery at a later date.

People used to think that a torn ACL could not heal, but new research suggests that healing is possible. The Cross Bracing Protocol uses a knee brace combined with rehab, with the aim of helping the ACL to heal. It does this by using a knee brace to hold the ACL in a position to heal naturally and protect it during the healing. This bracing protocol was developed in Australia by doctors Tom and Merv Cross and has now been used with over 880 people. In a research study of 80 people using this bracing treatment, nine out of 10 people had signs of healing of their ACL on MRI at 3 months after injury. It is possible that this healing can lead to better function and better quality of life compared with ACL surgery, but research is needed to understand if this is

the case. To find out whether the Cross Bracing Protocol or ACL surgery is better for people who tear their ACL, we need a study to compare these two treatments.

What is the aim of this study?

The main aim of this study is to compare outcomes (knee pain, symptoms, function and quality of life) between people with ACL rupture who are managed with the Cross Bracing Protocol, or with ACL reconstruction surgery.

Why is this study important?

Current treatments for ACL injury (rehab without surgery, or ACL reconstruction surgery) result in half of people feeling dissatisfied with their knee 2 years after injury. Better treatments are needed to improve outcomes for people with ACL injury. The recent discovery that ACL ruptures can heal without surgery allows new treatments to be explored with the aim of healing the ACL. A new bracing treatment has been developed in an attempt to assist the ACL with healing. It is not yet known how this bracing treatment compares which ACL surgery. Research is needed to compare this new bracing treatment to ACL surgery to guide treatment decisions for people with ACL injury.

3. What does participation in this research involve?

What is a clinical trial, and can I choose my treatment group?

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, a computer will put you into one of the two treatment groups by chance (at random, like flipping a coin). Neither the researchers nor you can decide which group you are in. As there are two treatments being compared in this study, you have equal possibility (a one in two chance) of receiving either one. This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way.

We suggest that your local doctor be advised of your decision to participate in this research project. If you have a local doctor, we recommend that you inform them of your participation in this research project.

Who can take part in this study?

You can take part in this research if you are **16 to 40 years old**, have **ruptured** (torn right through) your ACL **in the last 19 days** and have had (or are going to have) **an MRI scan of your knee to confirm this.** To take part, you need to be **willing to have either of the two treatments** being compared because you are not able to choose your treatment. This means you need to be willing and able to **pay any out-of-pocket costs** if you are allocated to the group having ACL surgery. The treatments and costs are explained in detail later.

Whichever treatment you have, please be assured that you will receive care for your ACL tear. You will continue with the same team of researchers, physios and doctors during your time in the study. These teams work closely together. They will be able to track your progress and share information with one another about your individual case during your time in the study.

There are several reasons that this study may not be suitable for you. These will be covered during screening and include:

- you have not finished all screening and filled in the first questionnaire 20 days after your ACL injury. This is because the injured knee must have the brace fitted by three weeks after your knee injury;
- your knee MRI scan shows that you have other knee injuries that need a surgical opinion;
- your knee MRI scan shows that the ACL ends are far apart, or your ligament has pulled right off the bone (this makes you less suited to the bracing treatment);
- you are not willing or able to have limited knee movement in the brace for 12 weeks;
- your knee MRI scan shows that your shin and/or thigh bone have not finished growing;
- you had an ACL injury or kneecap instability/dislocation on the same knee in the past;
- you had ACL or PCL surgery on the same knee in the past;
- you have a blood clot in your leg now or had a clot in your lung or leg in the past;
- you have medical problems that mean you cannot have ACL surgery, such as diabetes or heart problems;
- you are pregnant or plan to become pregnant in the first 12 weeks of being in the study. This is because you cannot have surgery while pregnant, and you cannot take the study blood thinner medication while you are pregnant or breastfeeding;
- you can't use medication that reduces the forming of blood clots. This may be because you are taking other medicines that can't be taken with the blood thinner, or you have a health problem or bleeding problem that does not allow you to take the blood thinner tablets;
- you are unable to speak or read English.

What is involved in the screening and consent process?

We will go through a screening process to see if this study is suitable for you. There are three (potentially four) steps in the screening. These are:

1. Answering some questions online
2. A discussion with a researcher on the phone
3. The study doctor looking at your knee MRI scan
4. A small number of people will be asked to have an ultrasound scan of their lower leg to check for blood clots

Online questions

By the time you read this information you may have already completed some of these steps. First, we will ask you to answer some questions online to check if this study is suitable for you. This should take around 10 minutes to complete. If you don't feel comfortable completing the initial screening questions online, you can instead telephone a researcher directly to complete the screening process over the phone.

Phone call with a researcher

If the online questions show that the study may be suitable for you, one of our researchers will telephone you and discuss the study in more detail. The phone call will take around 15-20 minutes. If the researcher thinks that the study may be suitable for you and you want to take part, you will be invited to sign the consent form online.

Study doctor looking at your knee MRI scan

Another part of screening involves a study doctor looking at your knee MRI scan to see if you are suitable for the study. If the online questions show that the study may be suitable for you, you will be asked for your consent to share your MRI images with the research team. If you provide your consent to share your MRI, the study Sports and Exercise Medicine Physician (sports doctor) or radiologist will access your scan through the radiology clinic.

If you have not had a knee MRI scan at that stage, you will need to have one to be screened for the study. You will need to get a referral from a doctor or physio (a GP or sports doctor referral is needed for this to be bulk billed), make an appointment at your preferred radiology clinic and have a knee MRI. You will need to pay for the GP appointment yourself.

After you let the research team know where you had the scan, the sports doctor will then access your MRI images by logging into the radiology clinic platform. A researcher will let you know whether or not the study is suitable for you based on your MRI findings. This may occur before or after the phone discussion with the researchers depending on timing.

If you do go on to take part in the study, the research team will keep a copy of the MRI scan of your knee in the study database so that measurements and information can be taken from it.

Ultrasound scan to check for blood clots
The last step in the screening is only if you report signs or symptoms of a blood clot in the leg, or if you have been on a plane flight or travelled in a car for more than 2 hours within 48 hours of injuring your knee, or more than 3 hours in a car at any time after that. You will receive a referral to have an ultrasound of your lower leg (calf) to screen for blood clots, which you will need to pay for. This is needed because you may have a higher risk of a deep vein thrombosis (DVT), which is a blood clot in a vein. If a blood clot is found before you enrol in the study, you will not be able to take part in the research. You will be asked to visit your GP or the closest Emergency Department as this will need urgent treatment. The study will not pay for costs related to treatment of the blood clot.

For you to take part in the study, we need to move through these screening steps as fast as we can. People need to be enrolled into the study and complete their first survey within 20 days of injuring their ACL. The reason for this is that the bracing treatment needs to start within 3 weeks of ACL injury to increase the chance of ACL healing.

After the screening is completed, you have signed the consent form and the first survey is filled out, the researchers will use a specialised computer program to find out which group you have been allocated to.

What surveys will I be asked to complete?

You will be asked to fill out a survey at the beginning of the study, then again 3, 6, 12 and 18 months after you enrol into the study. Completing these surveys is important as this allows us to compare outcomes between treatment groups. The surveys will be filled out online and will take about 20-30 minutes to complete each time. You can contact the research team if you need help. In the surveys, we will ask you about your knee pain and symptoms, as well as any problems you have because of your knee. We will also ask about your quality of life, general health, and treatments you have had for your knee.

Will I be asked to have MRI scans as part of the study?

You will already have had a knee MRI scan before you enrol in the study. If you are in the bracing group, we will ask you to have a knee MRI scan 3 months after you start in the study. This is to check on the healing of the ACL. You will receive a written report of these findings to discuss with your study physio. People in both groups will be asked to have a knee MRI scan 18 months after they start in the study. This will look at the ACL graft in the surgery group, and the amount of healing of the ACL in the bracing group. It will also look at the other structures inside the knee to check for any other knee injuries. You will receive a letter after the MRI with a summary of what was found and any recommendations. The study will cover the costs of the 3- and 18-month MRI scans.

What happens if I am allocated to the Cross Bracing Protocol treatment group?

What does the bracing involve?

People in this group will have their knee in a brace for 12 weeks (around 3 months). The brace is set to keep the knee bent at a right angle (90 degrees) for the first 4 weeks. For those 4 weeks, your knee will need to stay bent at a right angle all the time, even when removing the brace for showering or brace-free couch time. After four weeks, the brace is adjusted by your study physio to allow more and more knee movement each week. At week 10, the brace is adjusted to allow full knee movement. The brace is then taken off after 12 weeks. The brace that will be used is the SecuTec Genu knee brace, which is approved in Australia to treat knee problems.

BAUERFEIND **SecuTec Genu brace**

During the first 8 weeks in the brace, you will need to use crutches (or a knee scooter) to move around because you will not be able to straighten your knee to walk. Your physio will give you crutches and show you how to use them. You can choose to buy or hire a knee scooter or other mobility device (e.g. iWalker, wheelchair, walking frame, motorised scooter) instead of using the study crutches, but you will need to pay for this. Depending on your job, you may need to take time off. Desk-based jobs do not usually require any time off, while manual labour may need a few months off. Depending on the type of car you drive and the side of your injury, you may be unable to drive for the first 10 weeks. Your physio will tell you when it's safe to drive again. The study sports doctor can write you a medical certificate for work or to work from home, if needed.

Why is the knee held in a brace at a right angle (90 degrees)?

The Cross Bracing Protocol is different to other treatments that use rehab without surgery to manage an ACL rupture. When the knee is at a right angle (90 degrees), the two ends of the torn ACL are close to one another (reducing the gap between the torn ends of the ligament). The idea is that this may allow a bridge of tissue to form between the torn ends of the ACL and encourage healing of the ligament. This can be compared to how a broken bone is healed. The two broken ends of a bone are usually brought close together. They are then kept very still by putting the injury in a cast. This allows bone to form in a bridge across the gap and the break to heal. The same idea is used to help heal the ACL in the Cross Bracing Protocol.

Knee held in a brace at 90 degrees

What does rehab involve?

While you are wearing the brace and then after it is taken off, you will work with your study physio to do an exercise (rehab) program, in their clinic as well as at home. This rehab program will aim to keep the knee muscles as strong as possible while in the brace. It will then aim to improve the strength and control of your knee after the brace is taken off to help you return to your chosen sport or activities.

People in the bracing group will have 23 funded consults with a study physio. These physios work in private clinics across Melbourne, Sydney, Perth, Gold Coast and Brisbane. They have knowledge about helping people with ACL injuries using the Cross Bracing Protocol and have undertaken training about the study. The appointments will take place in person. You will need to be able to attend these appointments in person to be able to take part in the study. Telehealth can be offered for an occasional consult if you cannot make it to the clinic. The appointments will

be spread over the first 12 months of the study and will be funded by the study. If you are allocated to the bracing group, an overview of your study involvement is shown in Diagram 1.

Brace fitting appointment: The first appointment will take about 60 minutes. It will be with a physio who has had additional training in how to fit the brace. There are one or two of these physios in each participating city. This physio will work out the right size brace for you and fit it to your knee. They will provide you with crutches and exercise resistance bands. They will teach you how to look after your knee while you are wearing the brace, including checking for blood clots, using crutches, showering and getting safely up and down stairs. They will also give you exercises to do at home.

Follow up physio appointments: The rest of the appointments will take 30 minutes each and will be with a study physio. You will choose a study physio at a clinic that is the most convenient to you, and see this physio for all your funded physio consults. Your appointments may continue for the full one year, or you may finish physio earlier if you achieve your goals and return to your activities before one year.

The physio will work with you to develop personalised goals and give you exercises to work on strength, balance and movement whilst you are in the brace, and after it is removed. The key part of rehab is completing these exercises at home or in the gym at least two to three times a week for around twelve months. The physio will provide information about physical activity as well. Your study physio will let you know if you're ready to return to running, jumping, pivoting, and competitive sports. Of those people who return to sport, most do so around 12 months after injury, but everyone's recovery is different. We recommend people wait at least 12 months to return to sport, as waiting 12 months may allow more time for ACL healing.

If you decide to see a different exercise or rehab professional or have more than 23 appointments with your study physio, you will need to pay for these appointments yourself. There is more information about costs below.

What would I need to do to reduce the risk of a blood clot?

When an injured joint is held in the one position for some time, there is a higher risk than usual of a DVT (a blood clot) forming in the veins of the lower leg during this time. To prevent this from happening, your physio will show you exercises you can do to help the circulation and show you how to check for DVTs. You will also need to take a medication that helps to stop blood clots forming. The medication is called rivaroxaban. It is a tablet that you take once a day for the first 8 weeks in the brace. After 8 weeks you will be able to walk in the brace so the risk of a DVT is lower and this medication is no longer required.

Medications, drugs and devices must be approved for use by the Australian Federal Government. Rivaroxaban is a medication that is approved in Australia to prevent blood clots. However, in Australia it is not approved to prevent blood clots in people who have not had a clot before and who have not had recent surgery. It is not recommended for use in people under the age of 18 years in Australia, due to a lack of research in this age group. Despite this, it is still used in these ways. The reason for using this medication in this study is that although blood clots are rare, they can be very serious or even fatal, so we want to minimise any chance of this happening.

Before you start wearing the brace, you will have an appointment with a sports doctor at no cost to you. The sports doctor will explain how to take the blood thinner medication as well as discuss possible side effects. They will provide an e-prescription for the medication via email or text message. You will need to take this prescription to any pharmacy and collect the medication before your first physiotherapy appointment. You will need to pay for this medicine, but you will be reimbursed (paid back) by the research team in the form of a gift card or electronic transfer.

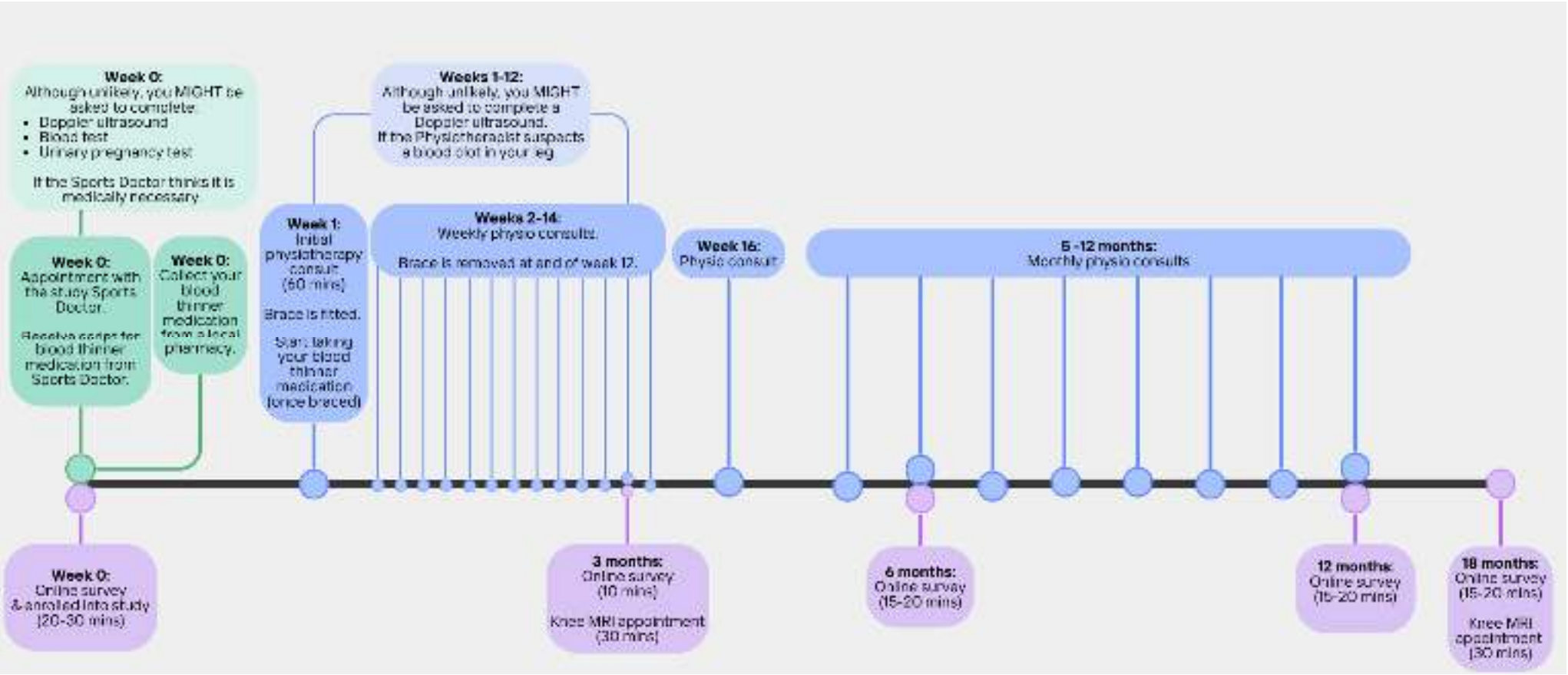


Diagram 1: Overview of study involvement for the bracing group

What if I decide to have ACL surgery?

As with any non-surgical ACL injury treatment, you will always have the option of an ACL reconstruction surgery if you decide this is something you want or need, after 12 weeks of bracing. If you are in the bracing group and decide to have any knee surgery, we cannot pay for any out-of-pocket costs related to the surgery. This includes ACL reconstruction surgery as well as any other knee surgery. However, you can continue to see your study physio for the full 23 appointments to help with your rehab after surgery.

The physio will help you to track your progress and assess your knee during your physio appointments. If your knee is unstable or gives way after completing the bracing treatment, the physio may suggest that you see an orthopaedic surgeon to consider having surgery. You will be provided with an appointment with the study doctor to discuss your progress. The doctor will be able to refer you to an orthopaedic surgeon or you may ask your GP for this referral.

If you are in the bracing group and have surgery during your 18 months in the study, it is still very important that you continue to have your study MRI scans and fill out your questionnaires. Your survey responses will help us to answer the question about which treatment helps people more.

What happens if I am allocated to the ACL surgery group?

People in this group will have ACL reconstruction surgery with a study surgeon within 8 weeks of enrolling in the study. The study surgeons will be Dr Nigel Hartnett and Dr Chris Kondogiannis (Melbourne), Dr Tim McMeniman (Brisbane), Dr Francois Tudor (Gold Coast), Dr David Parker and Dr Alex Nicholls (Sydney) and Dr Ross Radic (Perth**)**. The study doctor or your GP will provide a referral for you to see a study surgeon. You may need to share your address and Medicare number with us to include on a referral.

Your operation will be at a private hospital. You will have an appointment at the orthopaedic surgeon's rooms before your surgery. There may be a cost of up to $250 for the first appointment that is not covered by Medicare. The study will provide a total payment of $2000 towards costs related to your surgery. There is more information provided later about costs. All surgeons in the study are very experienced ACL surgeons, and you will receive the same care as if you were seeing the surgeon as a private patient outside of the study. This means that the surgery will not be different just because you are taking part in this study. The surgeon will explain the surgery and talk to you about your knee injury. As with any surgery, you will need to sign a separate consent form with the surgeon for the operation. The private hospitals where the surgeries are performed are not involved in the study and are providing the hospital services only, as they normally do for ACL reconstruction surgeries that are not part of this study.

What does ACL reconstruction surgery involve?
An ACL reconstruction is performed under a general anaesthetic. You will also meet with an anaesthetist before your surgery. The anaesthetist will use medications to put you to sleep during your surgery so that you do not feel pain during the operation.

Cuts are made at the front of the knee and the surgeon inserts a small camera and tools to do the operation. The surgeon will remove the torn ACL and drill tunnels into the thigh bone (femur) and shin bone (tibia) to attach the replacement ACL. The replacement ACL is a graft, which is tissue taken from elsewhere in the body. The ACL graft is placed into the tunnels in the bones and held in place usually metal buttons or screws. These do not usually need to be taken out. The operation usually takes 1 to 2 hours. Most people stay one night in hospital after their operation, but this may be different depending on which surgeon does your surgery.

Where is the graft taken from?
An ACL graft is a piece of healthy tissue taken from somewhere else in the body, that is used to replace the torn ACL. The most common ACL graft used is a piece of tendon taken from the hamstring muscle at the back of your thigh. Some surgeons use the middle third of the patellar tendon (this connects your kneecap to your shin bone) and bone from either side. More incisions may be required to remove this tissue.

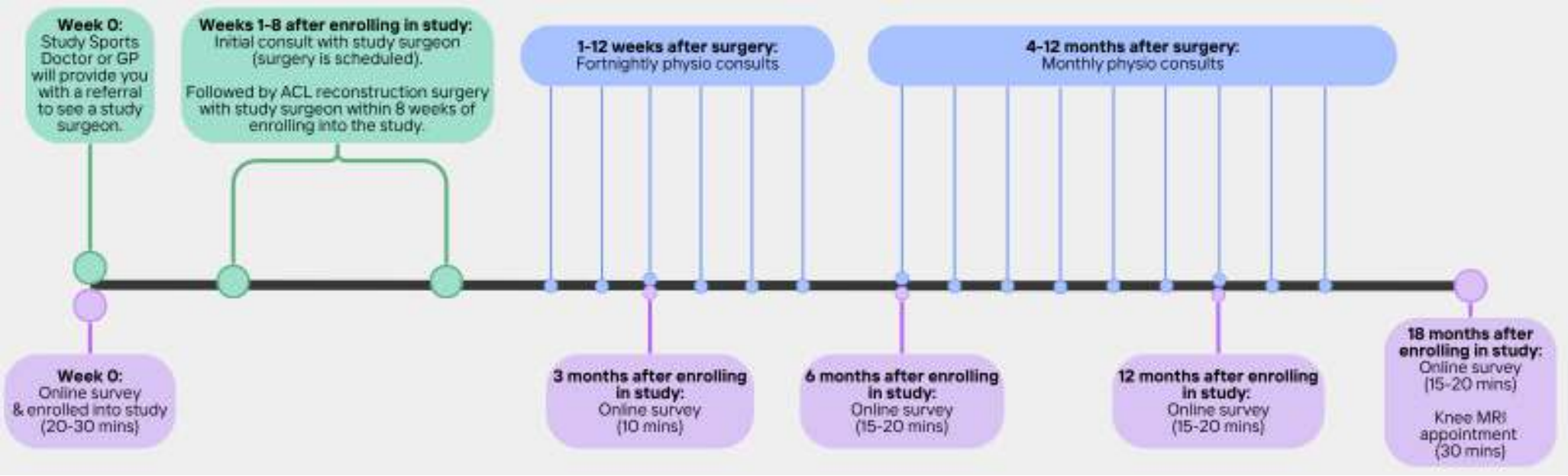
What happens after surgery?
After surgery, most people feel pain and are given painkillers. Your knee will be swollen and moving may cause discomfort. Moving the knee in walking is very important in this early stage to increase your ability to bend and straighten your knee and to work towards walking normally. You are likely to need crutches to move around for the first two weeks, and you should not drive for between two to six weeks. Your surgeon or physio will tell you when it's safe to drive again, depending on which knee was operated on and the type of car you drive. Depending on your job or studies, you may need to take time off. Desk-based jobs may require a two-week break, while manual labour may need a few months off. The study surgeon can write you a medical certificate for work or to work from home, if needed.

What does rehab after surgery involve?

After you go home, you will see a study physio for 15 funded rehab consults. The study physios work in private clinics across Melbourne, Sydney, Perth, Gold Coast and Brisbane. They have training and knowledge about treating people following ACL surgery and have undertaken training about the study. You will need to be able to attend these appointments in person to be able to take part in the study (telehealth can be offered for an occasional consult if you cannot make it to the clinic). The appointments will be spread over the 12 months after your operation and will be funded by the study. If you are allocated to the surgery group, an overview of your study involvement is shown in Diagram 2.

Your rehab will start straight after surgery. After surgery, you will spend one to two months focusing on managing pain, reducing swelling, strengthening your thigh muscles, and improving your ability to bend and straighten your knee. At first, your rehab will focus on reducing swelling, getting the knee moving again and working to switch on the muscles around your knee. As the pain and swelling in the knee improves, your study physio will set goals with you and give you exercises to work on strength, balance and movement. The key aspect of rehab is completing these exercises at home or in the gym at least two to three times a week for around twelve months. Your study physio will let you know if you're ready to return to running, jumping, pivoting, and competitive sports. Of those who return to sport, most do so around twelve months after surgery, but everyone's recovery is different. We recommend people wait until at least 12 months to return to sport, as waiting 12 months may allow more time for the ACL graft to heal.

Diagram 2: Overview of study involvement for surgery group



You may see your surgeon after your surgery, which will vary depending on the surgeon. The first physio appointment will take about 30 minutes, and the follow up appointments will also take 30 minutes each. You will choose a study physio at a clinic that is most convenient to you and see this physio for all your funded physio consults. The physio will work with you to develop personalised goals and a management plan. This will include an exercise program to do at home. They will provide information about physical activity and exercise that can be done as part of your rehab. They will give you advice and support to help you return to sport or activities depending on your progress and goals. Your appointments may continue for the full one year, or you may finish physio earlier if you achieve your goals and return to your activities before one year.

If you choose to see a different physio or decide to have more than 15 appointments with the study physio, you will need to pay for these appointments yourself. There is more information about costs below.

What costs are involved and what is being covered by the study?

MRI scan to look at your ACL injury

In Australia, the normal process to check someone's knee when they may have torn their ACL is to send them to have an MRI scan. This scan is funded by the government (Medicare) for people who are 16-49 years old, with a GP referral or sports doctor referral. Depending which radiology clinic you go to, you may need to pay an extra fee yourself ("out of pocket"). This will only happen if the clinic charges more for the scan than what the government will pay. The study does not pay for any costs related to this MRI.

If you are in the bracing group, you will be provided with the following free of charge:

- 23 appointments with a study physio
- an appointment with a sports doctor before you start wearing the brace;
- a specialised knee brace (Bauerfeind SecuTec Gen);
- an MRI scan of your knee at 3 months and 18 months after you enrol in the study;
- the blood thinner medication;
- a pair of crutches (if your study physio stores crutches at their clinic);
- a lower leg screening ultrasound, blood test and/or pregnancy test (once enrolled in the study, if the study sports doctor or study physio believes this is required);
- elastic exercise bands;
- an additional appointment with a sports doctor if needed throughout the 18-month study period.

If you are in the bracing group, things you will need to pay for yourself include:

- if you decide to have knee surgery during the 18 months of the study, we will not be able to reimburse you for any costs related to the surgery. If you choose to have this surgery in a public hospital (and have a Medicare card), this will be free of charge. We will still fund the 3- and 18-month MRI scans and 23 physio consults. You can use the remainder of the physio consults for your post-surgical rehab;
- if you choose to use a specialised scooter or other mobility (walking or movement) aid, you will need to hire or buy this yourself;
- you will need to pay up front for the blood thinner medication to take for the first 8 weeks.*
- if your study physio does not store crutches at their clinic, you will need to pay up front for the crutches.*
- you will need to pay up front for the urinary pregnancy test.*

  *We will reimburse you for blood thinner medication/crutches/pregnancy test in the form of a gift card or electronic transfer of funds. You will need to keep the receipt(s) to share with us if you would like an electronic transfer. You will also need to provide your bank details to the research team so that we can arrange reimbursement.

- if you decide to see a different exercise or rehab professional or have more than 23 appointments with your study physio, you will need to pay for these appointments yourself.

If you are in the surgery group, you will be provided free of charge with the following:

- a contribution of $2000 towards your out-of-pocket costs related to the surgery. Out-of-pocket costs are amounts that cannot be claimed back from Medicare, your private health fund or other insurance and would usually need to be paid in full by you;
- 15 appointments with a study physio after your surgery, to undertake your rehab program;
- an MRI scan of your knee 18 months after you enrol into the study;
- elastic exercise bands.

If you are in the surgery group, things you will need to pay for yourself include:

- any out-of-pocket costs relating to your surgery that are more than the $2000 contribution that the study will provide. These costs may include the "excess" on your private health insurance, appointments with your surgeon as well as any fees from the surgeon, the surgical assistant and the anaesthetist that are not covered by Medicare or other insurance. The cost for this will vary depending on your health fund and health professionals. If the study is found to be suitable for you, the research team can advise you how to find out how much this will be in your case before you decide whether to take part in the study. It usually ranges from $10,000 to $14,000;
- you may also need to pay for some medicines or crutches according to the private hospital policy where you have your knee surgery as well as your private health insurance rules. For example, you may need to pay for anti-inflammatory, pain or blood thinning medications prescribed by the surgeon to take home from the operation.

Other costs that all study participants may encounter:

- We will not pay you back (reimburse you) if you choose to attend extra physiotherapy appointments with your study physio, or if you choose to attend appointments with another health or exercise professional.
- You will need to pay for any additional knee surgery that you choose to have during the study period, unless you decide to have additional knee surgery in a public hospital.
- We will not cover the cost of any scans or tests except for those mentioned above.
- We are not able to provide payment for travel or parking, including any travel costs to attend physio or surgeon appointments, have knee MRI scans, or attend hospital.

Reimbursement for completing surveys

You will receive a $30 Coles-Myer (or similar) gift voucher after each of the follow-up surveys that you complete, as a token of appreciation of your time. These surveys will be 3, 6, 12 and 18 months after you enrol in the study. This means the maximum total amount you will receive in gift vouchers is $120.

Related studies and long-term follow-up

The research team may invite you to take part in an interview about your experience with your treatment and the study. This is a separate research project. You can decide at that time if you would like to take part in the interview study and would sign a separate consent form if so. We may also follow up with you in the future to see how your knee is going and to compare long-term outcomes between treatment groups. You will receive information about this in the future and you can decide then whether you would like to take part in this long-term follow-up.

4. Other relevant information about the research project

Are there any restrictions to my lifestyle as a result of taking part in the study?

Both treatments being used in this study to treat your ACL tear will affect your lifestyle. For the bracing group, there will be limits on your knee movement in the brace that will affect the way you move around and perform daily activities. The restrictions on driving and work have been described previously. You may need help with tasks around the home, including caring for small children, because of the limits on your walking and movement in the brace or after surgery. You may be unable to use stairs while you are wearing the knee brace and using crutches. If you have stairs in your home, we recommend discussing this with the research team to see if you would be able to take part in the study. If you are in the bracing group, you will need to have a chair in the shower so that you can sit while showering during the first 10 weeks. This is for your safety and will allow you to keep your knee bent at the required angle while you shower with the brace off. If you have concerns about this, we recommend discussing this with the research team before deciding to take part. As with any ACL injury, returning to sport is not typically recommended until around a year after injury.

How many people are involved in the study?

There will be 180 people taking part in this research. Around half of these people will be in the surgery group, and around half will be in the bracing group.

The experienced research team includes physiotherapists, a rheumatologist and an orthopaedic surgeon who work at universities in Melbourne, Sydney and Brisbane. The research team also includes a sports doctor and a knee specialist physiotherapist with expertise in the Cross Bracing Protocol, as well as people who have had an ACL injury.

5. Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, or your relationship with those treating you. You may withdraw any unanalysed data previously supplied by you.

6. What are the alternatives to participation?

You do not have to take part in this research project to receive treatment for your ACL tear. Other treatments are available as part of the usual treatment for ACL tears in Australia. An alternative treatment that is not offered as part of this study is trying rehabilitation without bracing for some time

(usually at least 3 months) before considering whether surgery is needed or likely to be of benefit to you. Studies suggest around 50% (half) of people do not require surgery if they try rehabilitation first. Some surgeons recommend that people who are not taking part in pivoting sport and older adults with lower knee demands try rehabilitation first, before considering surgery. If you think this may apply to you, we suggest discussing this with the research team or a health care professional. If you would like to try rehabilitation first, then this study is not suitable for you.

You may also choose to have ACL reconstruction surgery in a public hospital or with a private surgeon outside of this study. There are also some private physios and sports doctors who treat people with the Cross Bracing Protocol in Australia. You may also choose not to have any further treatment. The research team will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss treatment options with a sports doctor, a physio or a knee surgeon.

7. What are the possible benefits of taking part?

This study aims to further scientific knowledge and may improve future treatment of ACL tears. Your participation in this study will help us to find out whether the Cross Bracing Protocol or ACL reconstruction surgery is more effective for people with a recent ACL tear. Taking part in this study may also help other people who have an ACL injury as the findings may help to guide treatment decisions in the future. A potential benefit of taking part in this study is that you will receive care for your ACL injury that is funded by the study. Participants in both groups will receive a set number of consultations with a trained physio at no cost to themselves. These would typically cost $120-$150 per consult. Participants in the bracing group will also receive a knee brace valued at $750, crutches and exercise bands free of charge. A potential benefit for participants in the surgery group is a shorter waiting time for your first appointment with a surgeon as well as a contribution of $2000 towards out-of-pocket surgical costs, if undergoing surgery in a private hospital. Participants allocated to the ACL surgery group, who choose to have their surgery in a public hospital, will undergo surgery faster (within 8 weeks), than the typical wait-list time for ACL surgery (up to 18 months).

8. What are the possible risks and disadvantages of taking part?

Most medical treatments can cause side effects. The risks of treatments in this study do not differ from the risks of undertaking these treatments in the community. You may have none or some of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with the research team. Your study physio will also be looking out for side effects of the treatments.

There may be side effects that the researchers do not expect or do not know about and that may be serious. We recommend you contact the research team if you have any new or unusual symptoms that you think may be related to your treatment, and see your local GP or attend Emergency if you are concerned.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study team may need to stop your treatment.

Possible side effects of the bracing protocol

Knee pain and discomfort	Wearing the brace can cause some knee pain or discomfort, and it's possible you may experience skin irritation from wearing the brace. This usually settles once the brace is removed at 12 weeks.

Falls	There is a risk of falling over when you are in the brace because using crutches can be challenging.
Sleep disturbance	You will be provided with tips for sleeping in the brace, but it is likely that your sleep may be disrupted.
Knee stiffness	When the brace is removed, some people experience knee stiffness that can take a couple of weeks to correct.
Swelling of the injured lower leg	Some people notice that they have swelling in their lower leg and foot when they are not able to take weight through their injured leg, usually during the first 8 weeks of the program.
Muscle loss of your injured and braced lower leg	It is likely that there will be a loss of strength in the muscles on the injured leg, which improves with ongoing rehab.
Skin irritation/reaction to the brace	You may develop a skin irritation or pressure sores. Your study physio will help you with strategies to ensure the optimal fit and maximise comfort of your brace.
Blood clot (DVT)	A serious potential side effect of wearing the brace is a blood clot in a vein in your injured leg. The risk of a blood clot forming and causing problems is very low. Clots in the leg may require medical treatment in the form of injections or tablets to thin the blood. Very rarely, these clots can travel to the lungs (pulmonary embolus) causing breathing problems or even death. Out of 880 people who have been managed with the Cross Bracing Protocol, zero people who took the blood thinner medication experienced a blood clot in their lower leg and no-one experienced a blood clot in their lung. To reduce the risk, the study does not include people who have a high risk of a blood clot. People who have been on a flight or long car ride must have a scan to rule out a blood clot before taking part. Taking the blood thinning medication is important to reduce the risk of blood clots. Blood clots can also occur after ACL surgery, as outlined in the surgical risks below.
Rivaroxaban (blood thinner medication) side effects	Bleeding is the main side effect of the rivaroxaban medication that you will be asked to take for the first 8 weeks of the bracing treatment. There is no antidote available to reverse the effects of rivaroxaban, however there are things that health professionals can do to control or stop the bleeding. As with any medication, there are potential side effects that you should be aware of, and these include: • Bleeding • Heartburn/indigestion • Upset stomach: nausea, vomiting, diarrhoea or stomach ache • Longer and/or heavier than usual menstrual bleeding • Skin rash • Fatigue • Dizziness • Breathlessness • Fever • Yellowing of the skin and/or eyes (jaundice)

Possible side effects of the ACL reconstruction surgery

As with all types of surgery, there are some risks associated with ACL surgery. The surgeon and anaesthetist will provide participants with information about potential risks and complications before the surgery. Some risks you should be aware of include:

Risk	Explanation
Excessive swelling and bruising of the leg	This is due to bleeding in the joint and surrounding tissues. It can cause short term pain and make it difficult to bend the knee. Swelling usually settles within 8 weeks.
Infection inside the knee joint	The risk of infection is small, and occurs in around 1 in 200 cases. Treatment usually involves antibiotics (tablet or via drip) and may involve further operations to wash out the joint. Occasionally this can lead to joint stiffness, breakdown of the cartilage within the joint or failure of the graft.
Infection in the surgical cut/wound	The risk of infection in the skin or on the surface of the cut/surgical wound is small and occurs in around 1 to 2 in 100 people. Treatment usually involves antibiotic tablets.
Knee stiffness	This can result from scar tissue within the joint, and cause a in loss of movement. Treatment consists of physiotherapy or occasionally more surgery Full movement of the knee cannot always be guaranteed.
Bleeding	Small amounts of bleeding in the joint are normal. Large amounts of bleeding can occur but are more common in patients with bleeding disorders or those taking anti-inflammatory medications. These medications should be ceased 2 weeks prior to surgery. Excessive bleeding may require removal of blood/fluid from the knee using a needle or occasionally a repeat keyhole surgery.
Graft stretching	The graft can sometimes stretch over time and this can cause knee instability and giving way. This is more likely in people with ligamentous laxity (loose ligaments or very mobile joints) or in patients with damage to the other strong ligaments around the knee.
Blood clot (DVT)	The risk of a blood clot forming and causing problems is very low (2 in 100 people). Clots in the leg may require medical management in the form of injections or tablets to thin the blood. Very rarely (1 in 1000 people) these can travel to the lungs (pulmonary embolus) causing respiratory difficulties or even death. Blood clots can also occur with the Cross Bracing Protocol, as outlined above.
Damage to nerves or vessels	There are small nerves under the skin that cannot be avoided and cutting them can lead to areas of numbness in the skin below the knee. This is common. There can also be areas of tingling or that are extra sensitive around the scars. Any numbness generally gets smaller with time and doesn't affect your ability to function. Damage to nerves that control movement is extremely rare.
Problems with screws or other metal	The graft is fixed into place by metal screws, buttons or staples. These devices can occasionally cause irritation and require surgical removal.
Problems with the area that the graft is taken from	If the ACL graft is taken from the tendon of the hamstring muscle you can get some pain and swelling in the hamstrings at the back of the thigh but this is usually temporary. It is very rare to have any long-term hamstring pain. Ongoing hamstring weakness is possible. If the ACL graft is taken from the tendon below the kneecap, the biggest problem is pain at the front of the knee, which can cause discomfort with everyday activities, especially kneeling, running and jumping.
Ongoing pain	This can be unpredictable but is more common in people with damage to other knee structures. If unexplained pain does occur, then another keyhole surgery may occasionally be recommended.

Knee weakness	Some people experience long-term weakness in their knee and may not regain full strength in their thigh muscles after surgery, but this can improve with ongoing rehab.
Anaesthetic complications	Whilst anaesthesia is generally very safe there are some associated risks. The most common problems with anaesthesia are feeling unwell or vomiting, bruising at the site of injections, sore throat or hoarse voice. Most patients do not have these problems. If these problems do happen, they usually get better very quickly. Damage to teeth may occur, but this is rare. The risk of brain damage or death due to anaesthesia is very rare. The risk of problems from anaesthesia increases for patients who are having more major surgery, those with medical problems and those that require difficult anaesthetic procedures. If you have any concerns about these issues, you should discuss them with the study team.

The risk of re-injuring your ACL after treatment

There is a risk of further knee injury, or re-injuring the ACL, with all treatment options. After ACL surgery, graft rupture occurs in approximately 5-12% of cases (5 to 12 out of 100 people), and the risk is higher in people aged under 25 years, and in people who return to cutting and pivoting sports. If graft rupture occurs the knee may be unstable and further surgery may be recommended. Further operations are often more difficult and usually have worse outcomes than the first ACL reconstruction.

If you experience ACL healing with the Cross Bracing Protocol, there is also a risk of re-rupturing the ACL. Based on available data, it looks like the chance of this happening is similar to the chance of this happening after surgery. If you re-rupture your ACL, you may choose to have an ACL reconstruction. Some people have chosen to undergo the Cross Bracing Protocol a second time after re-rupturing their ACL.

Are there any risks related to conception, pregnancy or breast-feeding?

The effects of the blood thinner medication, rivaroxaban, on the unborn child and on the newborn baby are not known. Because of this, it is important that participants in the bracing group are not pregnant or breast-feeding and do not become pregnant while they are taking the blood thinners (usually the first 8 weeks of the Cross Bracing Protocol). You are not able to have surgery while pregnant either. If it's possible you might be pregnant, it is suggested that you have a pregnancy test prior to commencing the research project as pregnancy will make you ineligible to take part in the study.

Participants who could become pregnant are strongly advised to discuss with the study sports doctor about methods of effective contraception that are safe to use while taking the blood thinner medication.

If you do become pregnant whilst taking the blood thinner medication, you should advise the research team immediately. The study doctor will advise on further medical attention should this be necessary. You must not go ahead with surgery or continue the blood thinner medication if you become pregnant.

Could participating in this study cause me to feel upset or distressed?

An ACL injury can be a life-changing event, and people can experience a lot of emotions while they are recovering and undertaking rehabilitation, especially during the first year after ACL injury. No matter what treatment approach is taken, some people will be dissatisfied with their outcome and this can lead to negative emotions. These negative emotions are not specific to this study. However,

it is possible that the surveys that you will be asked to complete, which ask you to think about how your knee is feeling and the impact on your life, could make you upset. If you become upset or distressed as a result of your participation in the research, please contact the research team so they can direct you to relevant resources and health care professionals, if appropriate.

Are there any risks from the knee MRI scans?

An MRI scanner is a machine that uses electromagnetic radiation (radio waves) in a strong magnetic field. It will be used to take clear pictures of the inside of your knee. Electromagnetic radiation is not the same as ionising radiation used, for example, in X-rays. No ionising radiation is involved in these scans, but the use of magnetic field means that some people with implanted metal (such as pacemakers) cannot have them. You will need to complete a brief questionnaire (5 minutes) at the radiology clinic before your scan to make sure it is safe for you to be in the scanner. You will need to lie flat and still in the MRI scanner for around 10 minutes. The MRI scanner is very noisy and you will wear earphones to reduce the noise. Some people may experience symptoms of claustrophobia from lying in a confined space. If you do experience discomfort at any time during the scan, you will be able to alert staff by pressing on a call button provided to you.

There are no proven long-term risks related to MRI scans as used in this research project. MRI is considered to be safe when performed at a centre with appropriate procedures. However, the magnetic attraction for some metal objects can pose a safety risk, so it is important that metal objects are not taken into the scanner room. The radiology clinic staff will ask you questions to make sure there is no reason for you not to have the scan.

The scans we are taking are for research purposes. They are not intended to be used like scans taken for a full clinical examination. A specialist will look at your MRI scans for features relevant to the research project. On rare occasions, the specialist may find an unusual feature that could have a significant risk to your health. If this happens, we will contact you to talk about the findings. We cannot guarantee that we will find any/all unusual features.

9. What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the research team will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, the study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, the study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, they will explain the reasons and arrange for your regular health care to continue.

10. Can I take other medications and have other treatments during this research project?

Whilst you are participating in this research project, you may not be able to take some or all of the medications you have been taking for your condition or for other reasons. It is important to tell the study staff about any medications you may be taking, including over-the-counter medications, vitamins or herbal remedies. You should also tell the researchers about any changes to these during your participation in the research project. The researchers should also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

People in the bracing group will take blood thinner medication for the first 8 weeks. If you are in this group, you must make sure that your GP or pharmacist knows you are on the blood thinner before you start any new prescription medication or over-the-counter vitamins, supplements or medicines.

This is because some of these interfere with how the blood thinner works and may put you at risk of bleeding or having a clot. You should **not start** taking a **combined** oral contraceptive pill just before or while taking the blood thinner medication. You can't donate blood while taking the blood thinner and must wait two full days after you stop the medication before giving blood.

11. What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow a member of the research team to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the research team will not collect additional survey or MRI data from you. Survey and MRI data that is already collected will be kept to make sure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must let the research team know.

12. Could this research project be stopped unexpectedly?

Although it is very unlikely, this research project may be stopped unexpectedly for different reasons. These may include reasons such as unacceptable side effects, or being unable to find enough people to take part in the study.

13. What happens when the research project ends?

If you receive the Cross Bracing Protocol as part of this research, you may still go on to have ACL reconstruction surgery later if you and your health care team feel that this is required. Any costs associated with this would be paid for by you. The Cross Bracing Protocol is usually started within three weeks of ACL injury, so it is not recommended for people in the surgery group after the study ends.

You may choose to continue to see your study physiotherapist as needed, but please be aware that the study will only fund the number of physio consults as outlined above (15 for people in the surgery group and 23 for people in the bracing group). You may also choose to see a surgeon or sports medicine physician for management of your ACL injury after your 18 months in the study is finished but you will need to fund these appointments yourself, and may need to obtain a referral from your GP in order to claim a Medicare rebate for these appointments.

Once we have collected the information from all study participants and analysed it, we will send participants a summary of the overall study results. Depending on when you enrol in the study, the results may not be available for some time after you finish your final (18-month) survey. The study will take around four years to complete, with participants expected to enrol over a "recruitment" period of two years.

Part 2 How is the research project being conducted?

14. What will happen to information about me?

By signing the consent form you consent to the research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will be treated as confidential and securely stored on a

password protected University of Melbourne server. Information that could identify you, such as your name and address, is collected to allow research staff to stay in touch with you during the study and to invite you to take part in a longer-term follow-up study.

Before we analyse your information and survey responses, we will remove any information that identifies you and replace it with a code. Your information will only be used for the purpose of this research project and future related research. Information that could identify you will only be shared with your permission, or as required by law. De-identified study data will be stored indefinitely, to allow researchers to reanalyse data and answer new research questions in the future. Sometimes researchers request data from studies to combine with other research data and answer new research questions. If your study data is used for future research, we will ensure there is no information that could identify you within this data.

It is expected that the results of this research project will be published and/or presented, for example in medical journals and at conferences in Australia and overseas. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

The research team may access your test/scan results related to this study (MRI scans, ultrasound scans, blood tests or operation reports) held at radiology clinics, surgeons' private rooms or other health care providers for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

In accordance with relevant Australian and state privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request corrections to any information you disagree with. Please contact the study team member named at the end of this document if you would like to access your information.

15. Complaints and compensation

If you have a complaint about the conduct of the study, you could speak with the lead researcher if you feel comfortable doing so, or report this complaint directly to the ethics office that approved the trial. If you are not satisfied with the response of the lead researcher and/or ethics office, you could contact the University of Melbourne Research Integrity Administrator and/or make a complaint to the Office of the Australian Information Commissioner. Contact details for complaints are provided at the end of this document.

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital. In addition, you may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is serious and is caused by one of the parties involved in the study. You do not give up any legal rights to compensation by participating in this study. The University's clinical trials insurer provides No Fault Compensation cover which is similar in spirit and practice to the recommendations made by the Medicines Australia Compensation Guidelines. However, for the avoidance of doubt it is the University insurer's process which would be followed in the event of a claim.

16. Who is organising and funding the research?

This research project is being led by Associate Professor Stephanie Filbay at the University of Melbourne. It is funded by a grant from the Australian Government Medical Research Future Fund (grant number 2029933).

The University of Melbourne will receive a payment (grant funds) from the Australian Government Medical Research Future Fund to undertake this research project. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

Medibank Australia, the Australian Physiotherapy Association and the McKnight Family Foundation have also donated towards the cost of this project.

Declarations of interest

The experienced researchers involved in this study do not have any conflicts of interest related to this study. A physiotherapist who is part of the research team has been involved in training clinicians in the bracing treatment and could be perceived as having a conflict of interest. Dr Tom Cross is a study sports doctor and was involved in developing the Cross Bracing Protocol and could be perceived to have a conflict of interest. Dr Cross and the physiotherapist are involved in care of participants, but they will not be involved in analysing the study findings.

17. Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of the Royal Melbourne Hospital. The project has also been registered with the University of Melbourne HREC.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2023)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

18. Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the research team by contacting any of the following people:

Name / Position	A/Prof Stephanie Filbay – Principal Investigator Bridget Graham – Trial Coordinator Libby Spiers – Trial Coordinator
Telephone	03 9035 3027
Email	embrace-study@unimelb.edu.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	Research Integrity Administrator
Position	Office of Research Ethics and Integrity
Telephone	03 8344 1376
Email	research-integrity@unimelb.edu.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing Human Research Ethics Committee (HREC) approving this research and HREC Executive Officer details

Reviewing HREC name	Royal Melbourne Hospital HREC
HREC Executive Officer	Manager HREC
Telephone	(03) 9342 8530
Email	research@mh.org.au

Local HREC Office contact (Single Site - Research Governance Officer)

Position	Clinical Trials Governance Officer
Telephone	(03) 8344 2163
Email	clinicaltrials-governance@unimelb.edu.au

Consent Form - *Adult providing own consent*

Title	Evaluating non-surgical management of acute anterior cruciate ligament rupture with a novel brace protocol versus early surgical reconstruction – a comparative effectiveness randomised controlled trial
Short Title	The EMBRACE trial
Project Number	2024.149
Project Sponsor	The University of Melbourne
Coordinating Principal Investigator/ Principal Investigator	A/Prof Stephanie Filbay
Associate Investigator(s)	Prof Kim Bennell, Prof Rana Hinman, Prof David Hunter, A/Prof Adam Culvenor, Prof Ian Harris, Prof Nadine Foster, A/Prof An Tran-Duy, Dr Tom Cross, A/Prof Jane Rooney, Dr Matthew Dowsett, Ms Meike van Haeringen, Dr Rohan Sabharwal, Ms Fiona McManus, Dr Anurika De Silva, Ms Libby Spiers, Ms Gabrielle Knox, Ms Bridget Graham
Location	The University of Melbourne

Consent Agreement

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to The University of Melbourne concerning my ACL injury and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

- ❒ Consent was obtained via telephone with _____ (*Participant)* on ___/___/_____
- ❒ Consent was obtained via telephone with _____ (*Investigator)* on ___/___/_____